

119



No. 08-918

Supreme Court, U.S.
FILED

FEB 6 - 2009

OFFICE OF THE CLERK

IN THE
Supreme Court of the United States

R.J. REYNOLDS TOBACCO COMPANY,

Petitioner,

v.

STAR SCIENTIFIC, INC.,

Respondent.

**On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit**

BRIEF IN OPPOSITION

RICHARD McMILLAN, JR.
CLIFTON S. ELGARTEN
MARK M. SUPKO
MICHAEL I. COE
CROWELL & MORING LLP
1001 PENNSYLVANIA
AVENUE, N.W.
Washington, D.C. 20004
(202) 624-2500

CARTER G. PHILLIPS*
ERIC A. SHUMSKY
QUIN M. SORENSEN
PETER S. CHOI
SIDLEY AUSTIN LLP
1501 K Street NW
Washington, D.C. 20005
(202) 736-8600

Counsel for Respondent

February 6, 2009

* Counsel of Record

QUESTION PRESENTED

Whether the court of appeals correctly applied traditional standards of clear-error review when it concluded that the district court's findings of deceptive intent and materiality were unsupported by the evidence and therefore that respondent engaged in no inequitable conduct.

PARTIES TO THE PROCEEDING

Pursuant to Rule 29.6, Star Scientific, Inc. states that it has no parent company and no publicly traded company owns more than 10% of its stock.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
PARTIES TO THE PROCEEDING	ii
TABLE OF AUTHORITIES	iv
BRIEF IN OPPOSITION.....	1
COUNTERSTATEMENT OF THE CASE.....	2
REASONS FOR DENYING THE PETITION	10
I. THERE IS NO INTRA- OR INTER-CIRCUIT DIVISION OF AUTHORITY	11
II. THERE IS NO CONFLICT WITH ANY DECISION OF THIS COURT	19
CONCLUSION	24

TABLE OF AUTHORITIES

CASES	Page
<i>Anderson v. City of Bessemer City</i> , 470 U.S. 564 (1985)	21
<i>Applera Corp. v. MJ Research Inc.</i> , 372 F. Supp. 2d 221 (D. Conn. 2005)	16
<i>Aventis Pharma S.A. v. Amphastar Pharms., Inc.</i> , 525 F.3d 1334 (Fed. Cir. 2008)	14
<i>Batson v. Kentucky</i> , 476 U.S. 79 (1986).....	20
<i>Bristol-Meyers Squib Co. v. Rhone-Poulenc Rorer, Inc.</i> , 326 F.3d 1226 (Fed. Cir. 2003)	14
<i>Cargill, Inc. v. Canbra Foods, Ltd.</i> , 476 F.3d 1359 (Fed. Cir. 2007)	13
<i>Dennison Mfg. Co. v. Panduit Corp.</i> , 475 U.S. 809 (1986).....	23
<i>Digital Equip. Corp. v. Diamond</i> , 653 F.2d 701 (1st Cir. 1981).....	16
<i>E.I. du Pont de Nemours & Co. v. Berkley & Co.</i> , 620 F.2d 1247 (8th Cir. 1980)	16
<i>eBay Inc. v. MercExchange, L.L.C.</i> , 547 U.S. 388 (2006).....	22
<i>Ferring B.V. v. Barr Labs., Inc.</i> , 437 F.3d 1181 (Fed. Cir. 2006).....	11, 12, 18
<i>Holland v. United States</i> , 348 U.S. 121 (1954)	20
<i>Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.</i> , 488 F.3d 982 (Fed. Cir. 2007) .	14
<i>Huddleston v. United States</i> , 485 U.S. 681 (1988)	20
<i>Jackson v. Virginia</i> , 443 U.S. 307 (1979)....	20
<i>KSR Int'l Co. v. Teleflex Inc.</i> , 127 S. Ct. 1727 (2007)	22

TABLE OF AUTHORITIES—continued

	Page
<i>Kingsdown Med. Consultants, Ltd. v. Hollister Inc.</i> , 863 F.2d 867 (Fed. Cir. 1988)	13, 15
<i>Li Second Family Ltd. P'ship v. Toshiba Corp.</i> , 231 F.3d 1373 (Fed. Cir. 2000)	14
<i>McKesson Info. Solutions, Inc. v. Bridge Med., Inc.</i> , 487 F.3d 897 (Fed. Cir. 2007)	14
<i>Miller-El v. Cockrell</i> , 537 U.S. 322 (2003)	20
<i>Mitek Surg. Prods., Inc. v. Arthrex, Inc.</i> , 21 F. Supp. 2d 1309 (D. Utah 1998), <i>aff'd</i> , 230 F.3d 1383 (Fed. Cir. 2000)	16
<i>Pfizer, Inc. v. Teva Pharms. USA, Inc.</i> , 518 F.3d 1353 (Fed. Cir. 2008)	13
<i>Praxair, Inc. v. ATMI, Inc.</i> , 543 F.3d 1306 (Fed. Cir. 2008)	13
<i>Precision Instrument Mfg. Co. v. Auto. Maintenance Mach. Co.</i> , 324 U.S. 806 (1945)	23
<i>Schinzing v. Mid-States Stainless, Inc.</i> , 415 F.3d 807 (8th Cir. 2005)	15
<i>Zenith Radio Corp. v. Hazeltine Research, Inc.</i> , 395 U.S. 100 (1969)	23

REGULATIONS

<i>Notice of Proposed Rulemaking</i> , 56 Fed. Reg. 37321 (Aug. 6, 1991)	16
<i>Notice of Final Rulemaking</i> , 57 Fed. Reg. 2021 (Jan. 17, 1992)	16

RULE

<i>Sup. Ct. R.</i> 10	22
-----------------------------	----

IN THE
Supreme Court of the United States

No. 08-918

R.J. REYNOLDS TOBACCO COMPANY,

Petitioner,

v.

STAR SCIENTIFIC, INC.,

Respondent.

**On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit**

BRIEF IN OPPOSITION

The case-specific holding of the court of appeals does not warrant this Court's review. It does not implicate any conflict with opinions of other circuits or this Court concerning proof of intent, much less standards of appellate review. And, it manifestly does not raise questions of constitutional significance. Cf. Pet. 16, 30-31.

Rather, the sole issue is whether the record supports a factual finding, by clear and convincing evidence, that the patent applicant intentionally withheld material information during the prosecution of the patents-in-suit so that the patents are unenforceable under the doctrine of inequitable conduct. The district court found inequitable conduct based in large measure on a fanciful theory, advanced repeat-

edly by Petitioner, that four reputable law firms conspired to hide a single document from the Patent and Trademark Office (PTO). The Federal Circuit carefully and thoroughly reviewed the record and concluded that the district court clearly erred, which it did. This disagreement over the significance of the record evidence is inherently case-specific, and will have little, if any, impact on any future case. Accordingly, there is no legal principle for this Court to review, and the petition should be denied.

COUNTERSTATEMENT OF THE CASE

1. Harvested tobacco must be “cured” before it is ready for consumption in tobacco products. Pet. App. 2a-3a. Curing is typically done in barns, in which tobacco leaves are stacked and exposed to heated air, in the form of either the exhaust of burning fuel (a so-called “direct-fired” system) or clean air heated by a separate furnace (an “indirect-fired” system).

The curing process, however, can give rise to tobacco-specific nitrosamines (TSNAs), which, RJR agrees, “may be carcinogenic.” Pet. 4. The inventor of the patents at issue, Jonnie Williams, began exploring methods to eliminate TSNAs in the mid-1990s. Most curing at that time used a direct-fired system. Pet. App. 4a. Williams hypothesized that TSNA formation results from microbial activity on tobacco leaves during curing, and that this microbial activity is promoted by oxygen deficiency in the curing environment. *Id.* Under oxygen-depleted (anaerobic) conditions, microflora on the leaf surface take oxygen from nitrates in the leaves, thereby converting those nitrates into nitrites. Through other chemical reactions, the nitrites then form TSNAs. *Id.*

Williams found that adjustments to heat, humidity, or airflow would substantially prevent the formation of TSNA^s. He developed a process—improving on prior indirect-fired systems—for curing tobacco without depleting the environment of oxygen and thereby avoiding the microbial activity which leads to TSNA^s. Pet. App. 4a. This process resulted in individual TSNA levels of around 0.05 parts per million, substantially lower than the levels associated with direct- and indirect-fired curing systems. That discovery, which solved a problem that had bedeviled the industry for decades, formed the core of the patents-in-suit.¹ See *id.* at 4a-6a.

2. Four different and respected law firms assisted Williams, and his company Star, at various times during the patent application process and ensuing litigation. This interplay among the firms and Wil-

¹ The patents at issue, U.S. Patent Nos. 6,202,649 (“the ‘649 patent”) and 6,425,401 (“the ‘401 patent”), address an improved process for curing harvested tobacco leaves to reduce harmful nitrosamines in smoking tobacco. Claim 4 of the ‘649 patent, which the lower courts found representative of the asserted claims, covers:

A process of substantially preventing the formation of at least one nitrosamine in a harvested tobacco plant, the process comprising:

drying at least a portion of the plant, while said portion is uncured, yellow, and in a state susceptible to having the formation of nitrosamines arrested, in a controlled environment and for a time sufficient to substantially prevent the formation of said at least one nitrosamine;

wherein said controlled environment comprises air free of combustion exhaust gases and an airflow sufficient to substantially prevent an anaerobic condition around the vicinity of said plant portion; and

wherein said controlled environment is provided by controlling at least one of humidity, temperature, and airflow.

Pet. App. 9a.

liams formed a principal basis for the district court's finding of inequitable conduct.

a. Star was first represented in prosecuting the patents by Romulo Delmendo, then a senior associate at Sughrue Mion Zinn MacPeak & Seas, and now an Administrative Patent Judge. Williams and Delmendo met in August 1998 to discuss the invention and the application process. Pet. App. 4a. To assist Delmendo in understanding the science of curing and in drafting a patent application, Williams asked Harold Burton, a University of Kentucky researcher, to provide Delmendo with the scientific background of the invention. *Id.* Burton sent Delmendo a one-page letter on the subject. Williams did not review or receive the letter. *Id.* at 4a, 19a.

The Burton letter described Williams's hypothesis connecting TSNA formation to microflora growth and anaerobic conditions, and also stated that Burton had seen low TSNA levels in cigarettes he brought to the United States from China in 1997. Pet. App. 4a-5a, 47a-48a. It went on to speculate that these results might be attributable to "old curing technology that was abandoned in the U.S. during the sixties" but still used in China, including "radiant heat" systems in which pipes filled with hot air radiate heat throughout the barn. *Id.*

Delmendo filed a provisional application with the PTO in September 1998. Pet. App. 5a, 37a. He did not disclose or discuss Burton's speculations about older curing technology in the application because he concluded, after discussing the matter with Burton, that Burton knew little about the older curing technology, and virtually nothing about that technology as practiced in the United States. The application did indicate that some nations, including China, still utilize the radiant-heat method of curing, but stated,

based on Mr. Williams' belief, that "[the radiant-heat] process as applied to tobacco grown in the United States yields tobacco products with high levels of TSNA." *Id.* at 5a (alteration in original). This statement was based on an inference made by Williams from information he had received from another tobacco company, indicating that Brazilian tobacco cured using traditional indirect-fired techniques resulted in TSNA levels of 2.0 to 3.0 parts per million. *Id.* at 45a-46a. Prior to filing the provisional Delmendo confirmed the pertinent statement with Burton. Fed. Cir. App'x A217, 218, 226.

After the provisional application had been submitted, Williams later obtained tobacco samples from two farms in the United States, the Jennings and Currin farms, which still used indirect-fired curing methods. Pet. App. 5a-6a. The Jennings sample had been fully cured, and tests showed TSNA levels of 1.5 parts per million, see *id.* at 51a—less than TSNA levels commonly found in tobacco from direct-fired systems but still significantly above the low to undetectable levels produced by Williams's process. *Id.* The Currin sample had been only partially cured, and was microwaved before testing, which prevents TSNA formation; tests of this adulterated sample detected TSNA levels of 0.39 parts per million. *Id.* Williams reported the Jennings data to Delmendo, but did not discuss the less probative Currin data with him. *Id.* at 5a-6a.

In September 1999, Delmendo filed the non-provisional application that later issued as the '649 patent. That application added a disclosure, based on the Jennings data, that:

it is possible to somewhat reduce the TSNA levels by not venting combustive exhaust gases into the curing apparatus or barn. The preferred as-

pects of the present invention are premised on the discovery that other parameters, as identified above (e.g., airflow), can be adjusted to ensure the prevention or reduction of at least one TSNA regardless of the ambient conditions.

Pet. App. 6a-7a (emphasis omitted). Delmendo also removed the statement from the provisional application that "high levels of TSNA" would result from radiant-heat curing of tobacco grown in the United States. *Id.* at 17a n.7.

The non-provisional application was allowed on September 14, 2000. It was ultimately issued as the '649 patent on March 20, 2001. Pet. App. 6a-7a.

b. Shortly after the non-provisional application was filed, Star terminated the Sughrue firm for its patent prosecution work. The undisputed evidence showed that it did so because Star executives saw a Sughrue attorney clash unnecessarily with an examiner at an interview on another application, and because the senior Sughrue partner whom Star originally retained had become gravely ill. Pet. App. 7a, 18a.

Star thereafter retained a new firm, Banner & Witcoff, to handle its patent prosecution work. It also asked a third firm—Paul, Hastings, Janofsky & Walker, with which Star executives had a prior working relationship—to superintend an orderly transition of files from the Sughrue firm to the Fanner firm. Pet. App. 7a. Lawyers from the Banner and Sughrue firms met to discuss thoroughly the prosecution. The files, with the Burton letter in them, were then transferred wholesale to the Banner firm. *Id.*

c. On September 25, 2000, soon after the application for the '649 patent was allowed, the Banner firm filed a "continuation application," which later issued

as the '401 patent. The claims of the new application were related to those in the '649 patent but differed from them in certain (and, for purposes here, irrelevant) respects. Pet. App. 8a.

During prosecution of the '401 patent, the Banner firm and Star's litigation counsel, Crowell & Moring, were notified of the Burton letter and the Currin data, which had been disclosed to RJR in litigation over the '649 patent. Attorneys with the Banner firm examined the materials and decided that, particularly in light of other submissions already made to the PTO, they were immaterial. Pet. App. 8a-9a. They therefore did not disclose them to the PTO. The '401 patent was issued on July 30, 2002. *Id.*

3. Star filed suit against RJR for infringement on May 23, 2001, asserting claims under the '649 patent, and alleging that RJR had retrofitted many of its curing facilities, effectively stealing the patent's claimed process without Star's approval. A consolidated complaint to add claims under the '401 patent was filed soon after that patent was issued. RJR defended on several grounds, including that the patents were indefinite and were unenforceable due to inequitable conduct. Pet. App. 8a, 32a-33a.

An inequitable conduct trial was held in January and February of 2005. Some two-and-one-half years later, after pleas to the district court to issue a ruling and ultimately a mandamus petition to the Federal Circuit, the district court found inequitable conduct.² It concluded that, even if the Burton letter and the Currin data were not "*per se*" required to be disclosed,

² The district court also held the patent claims indefinite, and therefore invalid. Pet. App. 88a-89a. The Federal Circuit later reversed that aspect of the judgment, *id.* at 25a-29a, and the petition does not raise that issue here.

the information that other curing methods could produce "low to undetectable levels of TSNA" was material and deliberately concealed from the PTO. Pet. App. 51a, 71a. It specifically found that Star and Williams had switched from the Sughrue firm to the Banner firm, using Paul Hastings as an intermediary, in order to prevent the Banner firm from learning of the Burton letter and "to avoid 'tainting' the Banner firm with Delmendo's knowledge and concerns about disclosures to the PTO." *Id.* at 55a-57a. It rejected Star's explanation for the change, finding some testimony in this regard not credible and simply disregarding other testimony. *Id.* The district court then balanced materiality and intent, and held the patents unenforceable. *Id.* at 75-76a.

b. The Federal Circuit unanimously reversed. It properly stated the governing standard of review—clear error for factual determinations, and abuse of discretion for the determination of inequitable conduct as a whole. Pet. App. 12a. It properly noted that inequitable conduct requires proof by clear and convincing evidence of both materiality and deceptive intent. *Id.* at 13a. And, important here, it properly recognized that, "because direct evidence of deceptive intent is rarely available, such intent can be inferred from indirect and circumstantial evidence." *Id.* at 15a.

Applying this standard to the alleged misconduct, the panel concluded that the district court's finding of deceptive intent as to the '649 patent was "clearly erroneous." It recognized that the district court's finding was based in large measure on its acceptance of the "theory that Williams and Star conspired to deliberately prevent Delmendo and his colleagues at the Sughrue firm from disclosing the Burton letter to the PTO by replacing them with the Banner firm and

purposely keeping the Banner firm ignorant of the Burton letter." Pet. App. 17a, 48a. It concluded that this was error because, among other things, there were deficiencies in RJR's proof: "RJR failed to elicit any testimony or submit any other evidence indicating that Star knew what the Burton letter said prior to replacing the Sughrue firm, or that the letter was a reason for changing firms." *Id.* at 19a. Indeed, "RJR admitted at oral argument that it failed even to ask Williams or Star's other executives about these critical facts, and RJR failed to identify any testimony or other evidence when specifically asked by us to do so in supplemental briefing" that the court ordered at oral argument. *Id.*

It likewise found no evidence showing that Star had employed Paul Hastings to "insulat[e]" the Banner lawyers from the Sughrue lawyers, in light of the uncontradicted testimony (which the district court ignored) that lawyers from the Sughrue and Banner firms had met directly. Pet. App. 20-21a. "[T]he Banner firm was clearly given the Burton letter. Yet again, RJR failed to provide clear and convincing evidence to support its allegations." *Id.* at 21a. And, even if Star's explanation for the change in firms were not believed, "it remained *RJR's* burden to prove its allegation regarding the reason for the Sughrue firm's dismissal." *Id.* at 18a. There simply was "no evidence" from which an inference of deceptive intent underlying the change in firms could be drawn. *Id.* at 18a-19a.

Nor did other "facts and inferences relied on by the district court . . . plug this hole in RJR's evidence." Pet. App. 20a. The district court found that Delmendo had "concerns" about the materiality of the Burton letter, but no evidence at trial indicated that he expressed those concerns to Williams, *id.*, and ul-

timately he resolved them, *id.* at 5a. Nor did the statement in the provisional application, concerning TSNA levels in radiant-heat systems, provide clear and convincing evidence of deceptive intent because “provisional applications are not examined” and “the alleged misrepresentation was corrected prior to examination of the non-provisional application.” *Id.* at 17a n.7. The panel also noted that, “[t]o the extent the district court also relied on the nondisclosure of the Currin data,” the materiality of that data was clearly “questionable” and did not support a finding of deceptive intent as to the ‘649 patent. *Id.* at 21a n.9.

As for the ‘401 patent, the panel found the district court’s finding of deceptive intent weakened because it “was also heavily based on RJR’s ‘quarantine’ theory.” Pet. App. 22a. The panel, however, reversed the district court’s holding of inequitable conduct under the materiality prong. It found that the Burton letter and the Currin data were clearly “cumulative” to other references cited to the PTO during the prosecution of the continuation application that resulted in the ‘401 patent. *Id.* at 23-25a. Based on its holding regarding intent for the ‘649 patent, and materiality for the ‘401 patent, the panel reversed the judgment of unenforceability of both patents. *Id.* at 25a.

REASONS FOR DENYING THE PETITION

This intensely fact-bound case does not warrant this Court’s review. The petition’s claims of an intra- and inter-circuit division, and a conflict with decisions of this Court, are illusory. Even if there were a conflict, it is not implicated here because inequitable conduct could not be found on any standard, given the “major gap[s]” and “hole[s]” in RJR’s evidence. Pet. App. 19a-20a. Certiorari should be denied.

I. THERE IS NO INTRA- OR INTER-CIRCUIT DIVISION OF AUTHORITY.

The petition claims that the decision below “departs sharply” from prior opinions of the Federal Circuit, particularly *Ferring B.V. v. Barr Laboratories, Inc.*, 437 F.3d 1181 (Fed. Cir. 2006), which, it says, “view the materiality of withheld information as relevant in assessing intent” and “replace[the requirement of actual intent] with a lesser requirement that the applicant merely should have known of the materiality of the withheld reference.” Pet. 18. The decision below is entirely consistent with *Ferring* and similar cases.

1. In *Ferring*, which RJR did not cite below, the Federal Circuit affirmed a grant of summary judgment on the issue of inequitable conduct, concluding that the district court had properly inferred an actual intent to deceive. 437 F.3d at 1194. It based its conclusion on evidence that the withheld information was highly material and that “(1) the applicant knew of the information; (2) the applicant knew or should have known of the materiality of the information; and (3) the applicant ha[d] not provided a credible explanation for the withholding.” *Id.* at 1191.

Ferring did not obviate or lessen the requirement that deceptive intent be proven. Cf. Pet. 18. Although the court undoubtedly considered materiality in assessing intent, it did so in conjunction with other circumstantial evidence, including the applicant’s knowledge of materiality and explanation for withholding the material. See 437 F.3d at 1191-94. Certainly it never suggested that materiality alone could suffice to prove intent or that the two issues should be merged. To the contrary, *Ferring* specifically recognized that “materiality does not presume intent, which is a *separate and essential* component of ineq-

uitable conduct.” *Id.* at 1190 (emphasis added; alteration omitted).

Ferring was, in fact, nothing more than a specific application of the commonplace principle that intent may be inferred from circumstantial evidence.³ The decision below in no way departed from that holding. On the contrary, the panel cited *Ferring*, and stated directly (citing *Cargill*, another case relied upon by RJR for the putative intra-circuit split, see Pet. 19) that intent may be inferred from circumstantial evidence. Pet. App. 15a. The court did not “strongly suggest[],” Pet. i, much less hold, that materiality (or knowledge of materiality) cannot or should not be considered in assessing intent. To the contrary, in addressing the district court’s finding of deceptive intent, the materiality of the Burton letter was assumed and the court discussed extensively whether the applicant (the inventor Williams) and others had knowledge of the letter. E.g., Pet. App. 19a (“[A] review of the record shows that Williams actually testified . . . that he had never seen the Burton letter prior to his deposition in the present litigation.”).⁴ That same topic was explored at length at oral argument, and gave rise to supplemental briefs concerning knowledge. Fed. Cir. No. 2007-1448, Dkt. Nos. 45-48. The court of appeals also considered the explanations

³ Indeed, *Ferring* expressly did not articulate any rule extending beyond the specific facts before it. 437 F.3d at 1191. (“We need not in this case attempt to lay down a general rule as to when intent may be or must be inferred from the withholding of material information by an applicant.”).

⁴ In addition, the panel explicitly stated that the applicant’s failure to disclose the Currin data—on which the petitioner also relied for its inequitable conduct claim—could not support the finding of deceptive intent given questions over its materiality. Pet. App. 22a.

offered by the applicant and others for the failure to disclose the letter, and deferred to the district court's credibility determinations. Pet. App. 18a. In short, the panel considered precisely the same factors cited in *Ferring* (and other decisions cited by petitioners⁵), and simply arrived at a different conclusion, which was compelled by the record in this specific case.

Having determined that the district court clearly erred in concluding that RJR had proved a threshold level of intent, the panel properly reversed the finding of inequitable conduct without separately addressing the materiality of the information. The petition repeatedly notes that the panel "did not dispute" the materiality of the information, e.g., Pet. 16-17, 21, 34, the implication being that the Federal Circuit believed materiality irrelevant, or failed to address materiality when it ought to have done so. The former is mistaken, for the reasons just set forth. And the latter is no basis for certiorari, and is mistaken in any event. In *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, the Federal Circuit explained that it was "unnecessary to discuss materiality" when the district court's finding of intent was clearly erroneous. 863 F.2d 867, 872 n.5 (Fed. Cir. 1988).

2. The petition also argues that "[o]ther Federal Circuit decisions conflict with the decision below by permitting the consideration of materiality as evidence of intent, even where actual intent continues to be required." Pet. 19. Again, this seeks to manufacture a conflict where none exists.

⁵ Pet. 19; see *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1315-18 (Fed. Cir. 2008); *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 518 F.3d 1353, 1365-67 (Fed. Cir. 2008); *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1366-68 (Fed. Cir. 2007).

The petition's reliance on *Li Second Family Ltd. Partnership v. Toshiba Corp.*, 231 F.3d 1373 (Fed. Cir. 2000), is misplaced. Pet. 19. The excerpt it cites from *Li* merely states the unexceptional proposition that once threshold levels of materiality and intent have been established by clear and convincing evidence, these must be weighed by the district court to determine if the equities warrant a finding of inequitable conduct. 231 F.3d at 1378. Other cases cited by the petition say nothing any different,⁶ and the court below specifically reaffirmed this basic rule. Pet. App. 13a. Because RJR failed even to make the necessary threshold showing of intent, however, the panel properly held that it had no cause to review whether the district court abused its discretion when it balanced the equities. *Id.* at 13a, 16a, 19a; see also *id.* at 39a (district court recognizing the need for such a threshold showing). This record-specific question does not merit further review.

Petitioner fares no better with the remaining cases it cites. In each of these highly fact-bound decisions, intent was inferred from extensive circumstantial evidence. See *Bristol-Meyers Squib Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1239-42 (Fed. Cir. 2003); *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1344-49 (Fed. Cir. 2008). In *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, for example, it was "the overwhelming circumstantial evidence, coupled with the lack of any credible explanation for nondisclosure" that supported the finding of deceptive intent. 487 F.3d 897,

⁶ See Pet. 19-20 (citing, among other cases, *Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 999 (Fed. Cir. 2007) ("The more material the information misrepresented or withheld by the applicant, the less evidence of intent will be required in order to find inequitable conduct.")).

919 (Fed. Cir. 2007). Intent was not inferred merely from “[t]he high materiality of the withheld prior art coupled with the lack of a credible explanation for the nondisclosure,” as petitioner selectively quotes from that decision. Pet. 20 (alteration in original). The decision below states no legal rule that remotely constitutes a conflict with these cases.

The petition’s reliance on decisions in which counsel offered “no credible explanation” for their action is particularly inapt here. At trial, multiple lawyers from the two patent firms testified at length regarding their assessment of the Burton letter and their reasons for not disclosing it to the PTO. See *infra* at 18. The district court ignored that reasoned testimony, and instead fashioned an alternative theory which, as the court of appeals properly recognized, had no basis in evidence. Pet. App. 17a-21a.

3. There is likewise no division between the opinion below and decisions of other circuits, much less a “stark and longstanding circuit split.” Pet. 21-23.

The most recent circuit case identified in the petition was decided 28 years ago,⁷ and the currency of these decisions is doubtful. None of them has been cited in support of a “gross negligence” standard since the Federal Circuit’s 1988 *en banc* opinion in *Kingsdown*, which held that inequitable conduct cannot be inferred from grossly negligent behavior. 863 F.2d at 876. The Eighth Circuit, indeed, recently characterized *Kingsdown* as having “resolv[ed] conflicting precedent pertaining to gross negligence and intent,” see *Schinzing v. Mid-States Stainless, Inc.*,

⁷ See Pet. 22-23 (citing *Digital Equip. Corp. v. Diamond*, 653 F.2d 701 (1st Cir. 1981); *True Temper Corp. v. CF&I Steel Corp.*, 601 F.2d 495 (10th Cir. 1979); *Int’l Tel. & Tel. Corp. v. Raychem Corp.*, 538 F.2d 453 (1st Cir. 1976)).

415 F.3d 807, 813 (8th Cir. 2005), and applied the *Kingsdown* standard without reference to an arguably contrary pre-1988 Eighth Circuit case addressing patent invalidity based on allegations of “gross negligence,” see *E.I. du Pont de Nemours & Co. v. Berkley & Co.*, 620 F.2d 1247, 1268-70 (8th Cir. 1980). District courts in these circuits have consistently applied *Kingsdown* without referring to these older decisions or suggesting the existence of a circuit split. E.g., *Applera Corp. v. MJ Research Inc.*, 372 F. Supp. 2d 221, 225 (D. Conn. 2005); *Mitek Surg. Prods., Inc. v. Arthrex, Inc.*, 21 F. Supp. 2d 1309, 1317 (D. Utah 1998), aff’d, 230 F.3d 1383 (Fed. Cir. 2000) (table). And, PTO regulations dealing with fraud and the duty of candor—which were relied upon in several of the pre-1988 circuit decisions, e.g., *Digital Equip. Corp. v. Diamond*, 653 F.2d 701, 707 (1st Cir. 1981)—have since been amended to remove references to “gross negligence” in order to conform to *Kingsdown*. Notice of Final Rulemaking, 57 Fed. Reg. 2021, 2024 (Jan. 17, 1992); Notice of Proposed Rulemaking, 56 Fed. Reg. 37321, 37323 (Aug. 6, 1991).

The supposed “sharp and irreconcilable split” over this issue, if ever it existed, is stale. Notably, this Court has denied three prior petitions—including one from the decision in *Kingsdown*—raising this same issue. See Petition for Writ of Certiorari at 19-23, 28-31, *Nilssen v. Osram-Sylvania, Inc.*, 128 S. Ct. 2938 (2008) (No. 07-1293) (arguing that *Kingsdown* represented a departure from “a series of decisions in the 1970s and 1980s from the regional circuits and then the Federal Circuit”); Petition for Writ of Certiorari at 20-22, 24-25, *Ferring B.V. v. Barr Labs., Inc.*, 549 U.S. 1015 (2006) (No. 06-372) (alleging “a three-way regional circuit split on the showing of ‘intent’ necessary to trigger an inequitable conduct holding”); Peti-

tion for Writ of Certiorari at 24-26, *Hollister Inc. v. Kingsdown Med. Consultants, Ltd.*, 490 U.S. 1067 (1989) (No. 88-1562) ("The *in banc* Court simply overrules that entire prior body of law holding that intent to deceive may be found from the presence of gross negligence alone . . ."). Nothing in the petition in this case provides any reason not to follow this same course here. In the highly unlikely event that one of the regional courts of appeals decided this issue in conflict with the Federal Circuit, that would be the case that might warrant review.

4. Even if there were "confusion" regarding inequitable conduct within the Federal Circuit, Pet. 21, this case would present a particularly poor vehicle for considering it. This is because there was no inequitable conduct here under any standard. The district court based its finding of deceptive intent with respect to the '641 patent on three principal facts: (i) non-disclosure of the Burton letter, (ii) statements in the provisional application that radiant-heat systems in the United States yield high levels of TSNAs, and (iii) the purported conspiracy to change law firms to avoid disclosure of material information. See Pet. App. 46a-53a. But nothing in the record shows that Williams or others at Star were aware of the specific contents of the Burton letter or should have known to disclose it; the relevant statements in the provisional application were not considered by the PTO and, in any event, were clearly corrected in the non-provisional application; and all files held by the Sughrue firm were transferred to the Banner firm, with no evidence of an attempt to conceal anything. *Id.* at 17a-21a. The Federal Circuit was simply correct that the ultimate finding of deceptive intent was "clearly erroneous."

This is true even under the "should have known" standard advocated by RJR. See Pet. 18-19. Under any standard, there still must be proof that the patent applicant *knew* of the purportedly material information during the prosecution process. See *id.* at 18-21. But there was no evidence that Williams or others at Star knew of the specific contents of the Burton letter, as the Federal Circuit properly concluded after extensive and supplemental briefing on this question. Pet. App. 19a. Furthermore, *Ferring* itself recognizes that there is no inequitable conduct when an applicant presents a "credible explanation" why information was not disclosed. 437 F.3d at 1191; Pet. 18 (recognizing same). There was extensive testimony, all of which the district court ignored, about why Star's patent counsel determined that it was unnecessary to disclose the Burton letter and the Currin data. Pet. App. 5a, 6a, 8a-9a; Star Scientific Fed. Cir. Br. 28-29, 33-35, 38-39, 45-47; Fed. Cir. App'x A219, 224-25, 239, 240, 242, 253-54, 258, 264, 374, 378-80, 537-38.

And, most fundamentally, the information that RJR believes should have been disclosed here was utterly immaterial. The Burton letter contained uninformed speculation about Chinese tobacco, which would typically have been cured in a fashion significantly different from the "controlled conditions" that are at the heart of the patents-in-suit. Burton himself candidly testified at trial that he "d[id]n't have an idea" what TSNA levels in the United States would have resulted from curing with these now-abandoned methods. Fed. Cir. App'x A351; see also *id.* at A254, 518-19, 523, 533, 537-38.; Star Scientific Fed. Cir. Br. 27-30. As for the Currin data, both the district court and the panel expressly questioned the materiality of this information because the sample was not fully

cured and was then microwaved before testing, see Pet. App. 5a-6a, 21a n.9, precluding reliance on that information as proof of deceptive intent even under the petitioner's standard. The panel did not leave "undisturbed" the district court's findings concerning materiality, Pet. 13; it simply passed over these fact-bound and record-intensive determinations as unnecessary to its decision, see Pet. App. 18a n.8. There is no good reason for this Court to address these issues in the first instance.⁸

II. THERE IS NO CONFLICT WITH ANY DECISION OF THIS COURT.

Petitioner additionally claims a conflict with decisions of this Court regarding the use of circumstantial evidence, and indeed even the proper role of appellate courts. The decision below, however, nowhere purported to impose any limit on the consideration of circumstantial evidence, nor did it modify traditional principles of appellate review.

1. Far from rejecting circumstantial evidence as competent proof, see Pet. 23-25, the panel directly and explicitly acknowledged that such evidence may be relied upon in fact-finding: "because direct evidence of deceptive intent is rarely available, such intent can be inferred from indirect and circumstantial

⁸ The petition also challenges the determination that the Burton letter and Currin data were cumulative of other information disclosed during prosecution of the '401 patent, and therefore were not "material." See Pet. 34-35. However, it offers no support for its suggestion that the disclosed information should be ignored merely because it was submitted later in the patent prosecution process, and provides no basis for overturning the panel's conclusion.

evidence." Pet. App. 15a.⁹ Moreover, it went on to assess the circumstantial evidence from which the district court inferred improper intent. *Id.* at 17a-22a. Nowhere did it suggest, much less hold, that district courts may not infer intent from such evidence. The petition recognizes as much; whatever the Federal Circuit purportedly did wrong, the petition acknowledges that it did it "*sub silentio*." Pet. 24. The Federal Circuit's conclusion that the inference drawn by the district court in this particular case was clearly erroneous is error-correction that does not warrant this Court's attention.

The cases cited in the petition concerning circumstantial evidence are irrelevant. They arose in the criminal context, and involved such unrelated issues as proof of guilt, see *Holland v. United States*, 348 U.S. 121 (1954), the admission of extrinsic-act evidence, see *Huddleston v. United States*, 485 U.S. 681 (1988), and discrimination in jury selection, see *Miller-El v. Cockrell*, 537 U.S. 322 (2003). The factual analyses in those cases were based on the unique records at issue, and do not remotely cast doubt on the decision here. E.g., *id.* at 347 (concluding based on the record that the trial court committed "clear error" in its findings). That petitioner would even try to analogize this case to the due process decision in *Jackson v. Virginia*, 443 U.S. 307 (1979), or the equal protection holding in *Batson v. Kentucky*, 476 U.S. 79

⁹ See also Pet. App. 19a ("As noted earlier, the district court may infer facts supporting an intent to deceive from indirect evidence. *Cargill*, 476 F.3d at 1364. But no inference can be drawn if there is no evidence, direct or indirect, that can support the inference. RJR's lack of any evidence at all on the crux of its theory, let alone clear and convincing evidence, demonstrates that it failed to carry its burden.").

(1986), is itself ample proof that there is no real conflict.

2. Equally baseless is petitioner's claim that "[t]he Federal Circuit . . . ignored this Court's admonitions about the proper role of appellate courts in reviewing trial court factfinding." Pet. 25. The Federal Circuit recited the proper "clear error" standard of review, see Pet. App. 12a ("we review . . . factual determinations for clear error"), and applied that standard consistently, see *id.* at 18a ("credibility determinations are an aspect of fact-finding that appellate courts should rarely reverse").¹⁰ The petition identifies no relevant misinterpretation or misstatement of law. It criticizes the Federal Circuit for not quoting the "any rational trier of fact" due process standard from *Jackson*, see Pet. 25, but neither explains how the *Jackson* formulation differs from the clear-error standard stated by the panel or, more importantly, why the Federal Circuit was required to cite *Jackson*, particularly when prior cases from this Court—and petitioner's own brief below—address that standard without reference to *Jackson*. E.g., *Anderson v. City of Bessemer City*, 470 U.S. 564, 573-76 (1985).

In sum, the petition raises only a disagreement with the appellate court's analysis of the record, see Pet. 25-27, including supposed errors of omission, e.g., *id.* at 26 ("the Federal Circuit did not even acknowledge the trial court's explicit rationale"). But such a fact-laden dispute simply does not implicate

¹⁰ Far from having given "no deference to the . . . credibility judgments by the trial judge," specifically concerning "inventor Williams," Pet. 26, the panel expressly accepted the district court's assessment of Williams's credibility for purposes of analysis, Pet. App. 18a-19a.

"the proper role of appellate courts." *Id.* at 25. Even if the court of appeals' analysis were not absolutely correct—and it is—the correction of "erroneous factual findings" or the "misapplication of a properly stated principle of law" is not a proper basis for certiorari. Sup. Ct. R. 10.

3. Petitioner also argues that review is warranted to reaffirm that "well-established principles governing appellate review of trial court factfinding" govern patent cases and "to make clear that there are no special limitations upon the trial court's assessment of circumstantial evidence of intent applicable to inequitable conduct or to patent cases." Pet. 27, 29-30. No such clarification is necessary. The Federal Circuit did not hold that clear-error review applies differently in patent cases or that any "special limitations" restrict consideration of circumstantial evidence in patent cases. To the contrary, it cited traditional principles of appellate review and standards for assessing circumstantial evidence. See Pet. App. 12a, 18a. That the petitioner disagrees with the court's conclusions, and its reading of the factual record, does not constitute a "conflict" worthy of review.

Petitioner cites various patent cases in support of this supposed conflict, none of which is at odds with the decision below. Pet. 27-29. The questions presented in both *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006), and *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), concerned whether the Federal Circuit had properly defined the relevant *legal* standard for, respectively, an award of injunctive relief and a finding of "obviousness." 547 U.S. at 391-93; 127 S. Ct. at 1742-43. *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machine Co.* was part of the early line of cases first recognizing the defense of inequitable conduct and defin-

ing the bounds of the doctrine; the facts of the case were considered as a necessary incident to discussion of the legal standard. 324 U.S. 806, 814-19 (1945). At issue in *Zenith Radio Corp. v. Hazeltine Research, Inc.*, was whether an individual may be bound by a prior judgment in litigation to which the individual was not a party; only after addressing this legal issue did the Court review the lower courts' assessments of the factual record. 395 U.S. 100, 108-12 (1969). And, finally, in *Dennison Manufacturing Co. v. Panduit Corp.*, 475 U.S. 809 (1986) (per curiam), this Court granted the petition and vacated the judgment not because the court of appeals had "substitut[ed] its view of factual issues for that of the District Court," Pet. 29 (alteration in original), but because the Federal Circuit had not addressed the unresolved question of the proper standard of review. 475 U.S. at 811. No such issue of law is presented here.

The petition also suggests that this case necessarily implicates important federal questions and warrants review because it concerns the issuance and validity of a patent—an issue supposedly "of constitutional dimension." Pet. 30-32. This is clear overreaching. Not every patent case merits this Court's review, nor does every party's disagreement with factual findings concerning patent litigation justify certiorari. A patent case, like any other, warrants review by this Court only if it reflects a split of authority, conflicts with decisions of this Court, or presents an issue of exceptional importance to the administration of federal law. This case satisfies none of these standards. It turns on nothing more than that "RJR failed to carry its burden of proof." Pet. App. 20a; see also *id.* at 19a, 21a.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted,

RICHARD McMILLAN, JR.
CLIFTON S. ELGARTEN
MARK M. SUPKO
MICHAEL I. COE
CROWELL & MORING LLP
1001 PENNSYLVANIA
AVENUE, N.W.
Washington, D.C. 20004
(202) 624-2500

CARTER G. PHILLIPS*
ERIC A. SHUMSKY
QUIN M. SORENSEN
PETER S. CHOI
SIDLEY AUSTIN LLP
1501 K Street NW
Washington, D.C. 20005
(202) 736-8600

Counsel for Respondent

February 6, 2009

* Counsel of Record